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The State Of The Art

By Allan Showalter, MD

The No-Nonsense Summary
The State Of The Art

1. ***Compliance theories & programs have thus far had little impact on day to day clinical practice***

2. ***Some compliance enhancement programs & models work with some patients some of the time, but none work with all patients all the time***

3. ***Theories of adherence based on patients who behave rationally lead to the clinically & ethically flawed classification of patients, vis-à-vis compliance, as "Good Patients" "Bad Patients" and "Pitiful Patients"***

4. ***All important contemporary theories of adherence are based on patients who behave rationally***

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Contemporary Medical Compliance Program Design, Theoretical Models Of Medical Compliance, & Their Limitations

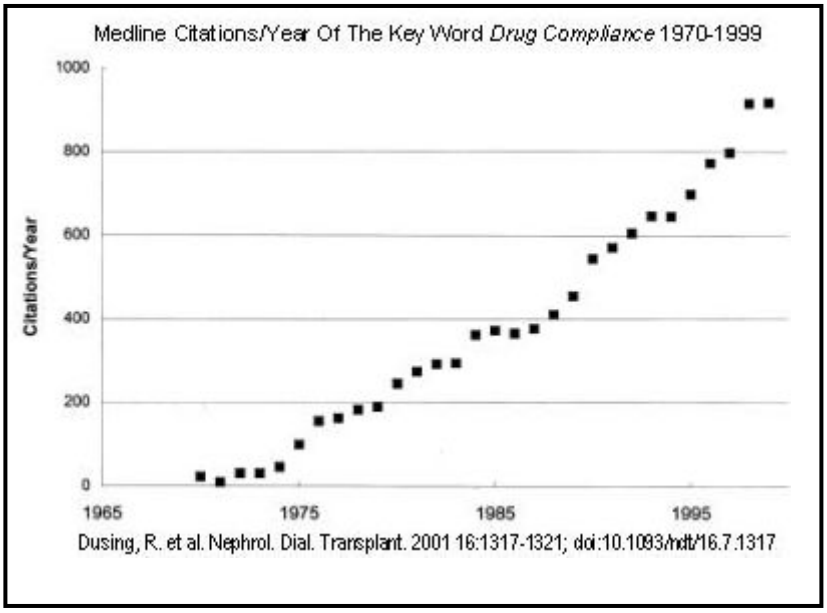
Clinicians have battled noncompliance since at least the fifth century BC (and no doubt long before that) when Hippocrates advised physicians to "keep watch also on the faults of the patients which often make them lie about the taking of things prescribed."

Theories explicating noncompliance have been generated, adapted, and revised; automated reminders and medication dispensers constructed and sold; courses in doctor-patient communications and empathy added to the medical school curriculum; public service announcements featuring celebrities broadcast; four-color national magazine spreads printed; call centers staffed; brochures, films, and tapes distributed; web sites created; disease management programs developed; and laws passed, all in the hope of improving adherence.

The Verdict

These labors have resulted in an impressive number of papers published (a Medline search for "patient compliance" turns up more than 27,000 articles over the past 20 years; and the chart below by Dusing et al indicates the pace of such publications is accelerating), a similarly impressive internet presence established (Google shows about 408,000 hits for "patient compliance"), numerous post-graduate degrees earned, some positive PR generated, and, occasionally, an isolated, situation-specific improvement in compliance rates.

None of this, however, has led to reproducible methodologies that can reliably and enduringly enhance compliance. Nor has a foundation been laid for the progressive growth of knowledge about and ability to manage treatment adherence.



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The most damning evidence of the practical ineffectiveness of contemporary compliance enhancement theories and programs is the absence of their influence on day to day clinical practice. My experience as well as that of my colleagues over many years of medical practice in various settings, locations, and specialties is that patient compliance is only rarely a discrete topic in clinical settings or an issue that comes quickly to the minds of most clinicians, even in situations, such as treatment failure, in which noncompliance is a likely, and perhaps, ***the*** likely cause. Even fewer clinicians (other than those treating a few special populations, such as HIV infected patients and organ transplant candidates) implement specific interventions with the goal of managing noncompliance.

Still, it is admittedly tricky to prove the absence of an effect on a system as ambiguous, variegated, and unwieldy as American healthcare. A reasonable proxy, however, is available; the following passages are drawn from medical literature dealing with compliance and not only summarize the findings of the article from which they were excerpted but are also representative of the overwhelming majority of scholarly and clinical reviews on the topic.

> *Most methods of improving adherence have involved combinations of behavioral interventions and reinforcements in addition to increasing the convenience of care, providing educational information about the patient's condition and the treatment, and other forms of supervision or attention. Successful methods are complex and labor intensive, and innovative strategies will need to be developed that are practical for routine clinical use.*[1]

> *Several complex strategies, including combinations of more thorough patient instructions and counseling, reminders, close follow-up, supervised self-monitoring, and rewards for success can improve adherence and treatment outcomes. However, these complex strategies for improving adherence with long-term medication prescriptions are not very effective despite the amount of effort and resources they consume.*[2]

> *The conundrum of compliance is extremely complex, and as yet whilst there are possible indicators as to some possible understandings and explanations, amongst some patients, in some contexts, with some areas of treatment/advice, these are still rather theoretical. Despite the wealth of research into determinants and management of compliance, few simple conclusions can be drawn.*[3]

> *It is unlikely that there will ever be a "cure" for noncompliance. No single, specific strategy that will enhance compliance in all patients—or even in the majority of patients—has been found. Compliance researchers agree that a range of strategies must be used, targeted to the underlying cause or causes of noncompliance and tailored to the needs and circumstances of each individual patient*[4]

> *No single approach to improving adherence can be recommended on the basis of the evidence reviewed. Complex interventions may improve adherence and control in difficult patients. Worksite, nurse-led, protocol-guided care may have some advantages over usual care in younger men. Unfortunately, the wide variation in the types of intervention used and the outcomes measured make statistical meta-analysis methods inappropriate.*[5]

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So there it is. After almost 2500 years of pondering, healthcare's consensus is that *compliance problems are complex*, and the *most promising solutions are also complex*, as well as *impractical and diverse*, with *no sure means of determining which interventions are most likely to work for a specific patient*. And, few reviewers confidently endorse any specific tactic without extensive hedging.

To understand the problem underlying orthodox notions of patient compliance, it is useful to examine some examples of these theoretical models and programs.

Overview of Current Compliance Models

Several hypothetical models of healthcare compliance have been developed which are appealingly straightforward, logical, and internally consistent. Moreover, they seem to provide genuine insight into certain features of patients' responses to healthcare recommendations. Yet, as already noted, their impact on routine clinical care has been negligible. This ineffectiveness, we propose, is secondary to an element common to all of these models: each of these hypothetical constructs postulates a patient who functions solely and invariably in a logical manner. Without such an individual, the models' mechanisms, however elegant, will not operate.

Three of the most influential models, The Health Belief Model, The Transtheoretical Model, and Learning Theory, are illuminating in this regard. (Caveat: The descriptions that follow are illustrative rather than complete and are not presented as well-rounded examinations. A more thorough, yet still succinct, summary of all the most important models can be found in Elder's "Theories and Intervention Approaches to Health-Behaviour Change."[6])

The Health Belief Model, for example, is predicated on the ability of a rational individual to consciously weigh advantages and disadvantages of a given behavior holds that the extent to which an individual will follow a healthcare recommendation is a function of his set of beliefs regarding that recommendation. According to this model, a patient will adhere to a treatment regimen if he believes the health problem being treated is significant, the prescribed treatment is likely help, and he (the patient) is able to implement the recommended course of action. The most common intervention based on this model is a discussion between the patient and the clinician of the pros and cons of undertaking the recommended behavior, followed by the patient's decision regarding treatment.

The Transtheoretical Model's starting point is the assumption that health behavioral changes are the result of a logical process, which is divided into five stages:

1. *Precontemplation*: The individual has yet to consider a change possible or needed
2. *Contemplation:* The individual grasps the problem and considers change
3. *Preparation:* The individual plans to act on the change within the ensuing month
4. *Action:* Contemplation and preparation are transformed into actual changes
5. *Maintenance:* The goal becomes sustaining behavioral change and resisting relapse

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Learning Theory promotes an analogous methodology of breaking down complex healthcare-pertinent behavioral changes into small steps that can be sequentially established (learned) and reinforced.

Clearly, an absolute requirement for each of these theories (as it is for the other compliance models) is an individual who operates in a predominately logical manner. In fact, the intuitively assessed validity of these models correlates precisely with the degree of rationality one assigns to an imaginary patient; a convincing argument can be made that the ideal subject would be a rudimentary artificial intelligence machine – or *Star Trek's* Dr. Spock. The implicit goal of these theories appears to be assisting individuals who already operate on the basis of logical calculations make those calculations even more logically. That is no small accomplishment, nor is it irrelevant to compliance.

It just isn't enough.

The nature and consequences of this logic-dependency are discussed in a later Section, Good Patients, Bad Patients, Economic Man, & Other Nonexistent Species. Before that, however, it is necessary to consider real world applications – the programs and tactics used to enhance compliance.

Overview of Current Compliance Program Design

While a relatively limited number of theoretical models of compliance has been accepted by consensus, and expositions, reviews, and critiques of each are readily available, programs and interventions promoting adherence are ambiguously defined, often operate in obscurity or are initiated with fanfare and surreptitiously terminated, and typically do not meet the standards for scientific investigation, even when they are described and catalogued as research. Peterson's meta-analysis of trials of interventions to improve medication adherence, in fact, found that only 61 of 484 pertinent studies met minimal inclusion criteria as randomized, controlled trials with at least 10 subjects per intervention group.[7]

Interventions may require complex and extensive staffing and monitoring logistics, consist of no more than a printed sheet of information, or call for the equipment ranging from a give-away plastic pill box with compartments for each day of the week to wristwatch alarms to timed medication dispensers to internet connected devices that alert the patient that a dose is due, electronically documents that the medication was dispensed, provides informational prompts to the patient, and warns if a dose is missed or taken at the wrong time. (Links to these and other compliance devices can be found in the AlignMap FURL Archive, under the category, *Enhancement Of Compliance*.) Other compliance enhancement interventions include but are assuredly not limited to

- One on one counseling provided by a pharmacist, nurse, educator, or physician
- Educational videos, brochures, and tapes presented to individuals or groups
- Court mandated and monitored treatment
- Promotions of self-reliance and self-efficacy
- Improved patient-clinician communications

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- Directly observed therapy (e.g., treatment for Tuberculosis)
- Mechanical or electronic reminders with visual or auditory cues
- Adherence programs provided by a pharmaceutical manufacturer and often limited to a single medication
- Automated or personal phone calls or email
- Disease management programs
- Celebrity endorsements
- Public Service Announcements in broadcast media or publications
- Simplification or alteration of regimes
- Assistance to increase accessibility (e.g., increased clinic hours, transportation, home services, etc)

This diversity and the large number interventions precludes an exhaustive critique of each. Some generalizations are, however, possible:

- As is the case for the theoretical models, many of these interventions depend on a cogent, rational patient
- A large proportion of the interventions are based on the notion that noncompliance is the result of a lack of understanding and is best addressed by education. Research findings and clinical experience, however, indicate that education, even when successful, is often insufficient to correct noncompliance.
- Similarly, many interventions are reminders, designed to combat forgetfulness, inattention, and absent-mindedness. Even when these are significant problems, reminders are no panacea.
- Perhaps the strategy receiving most attention is reorganizing the clinician-patient relationship such that the patient's role is more assertive, collaborative, and proactive. This has proved a difficult for both clinicians and patients, and the results are not universally positive.

Good Patients, Bad Patients, Economic Man, & Other Nonexistent Species

The consensus view gleaned from research and clinical experience toward these theories and programs can be summarized in a Lincolnesque aphorism:

> ***Some compliance enhancement programs and models work with some patients some of the time, but none work with all patients all the time.***

And, as it turns it, none work with most of the patients most of the time. It is especially discouraging that, even when potentially helpful methodologies are available, we are unable to predict which patients will respond to which methods.

The problem with the hypothetical models of compliance and compliance programs is that they beg the question of how real patients in real clinical situations decide to follow – or not follow – a specific treatment. The orthodox medical perspective that patients first make a careful analysis of the benefits and risks of each course of action and then choose the

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alternative with the best ratios of pros (anticipated health benefits) to cons (fiscal and non-fiscal costs associated with compliance, including side-effects, discomfort from feelings re use of medication, reluctance to accept the sick role, …).

This kind of assumption leads to researchers developing mathematical representations of the patient's decision-making process; for example, one paper conveniently condenses the "probability of noncompliance" to

$$Pr(nc^*(j,p)=1) = Pr(w_{jp} \le y_j) = F_j(y_j)$$

and the patient's calculation of the pros and cons of compliance to

[8] $$\overline{UP}(nc;j,p) = E_{\omega_1,\omega_2}[UP(nc;j,p)|p,j,nc] = \begin{cases} u_p & \text{if } nc=1 \text{ (do not comply)} \\ \theta_{jp} - \overline{u}_{jp} & \text{if } nc=0 \text{ (comply)} \end{cases}$$

That such formulas appear to be gibberish to those of us who struggled with pre-med calculus does not, of course, necessarily rule out their capacity to generate insight into medical compliance. On the other hand, the idea that such mathematical equation directly reflects an individual's decision-making triggers, at least in me, a severe case of cognitive dissonance

A consideration of an analogous situation is helpful. The rational patient who populates theoretic models of compliance is closely related to the "economic man" who once inhabited economic theory, behaving exclusively on the basis of perfect understanding of perfect data used in a perfectly logical and reasonable manner to optimally satisfy his self-interest.

In fact, if a purebred economic man ever existed, it was in a land far away and a time long ago. At best, the economic man is an oversimplified ideal, useful in generating theory but inadequate to account for real life behavior. Instead, most economists, all stock brokers, used car dealers, eBay merchants, and anyone making a living in retailing, advertising, or marketing have long recognized that emotions, cultural beliefs, self-concept, altruism, personality factors, social mores, and other forces, albeit often disguised as rational determinations, are significant influences when an individual selects a brand of cereal or chooses a spouse or adheres to a doctor's recommendations.

While few economists would intentionally base their recommendations and predictions on the concept of the economic man, most clinicians and researchers, however, still seem to subscribe to the notion of a universe of healthcare populated by logical patients, who, even in the midst of the incapacity and distress caused by their disorder, operate exclusively on the basis of intellectual and rational processes to choose and execute their treatments.

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Two indictments of the "economic man" model statements by economists are equally applicable to healthcare:

Ernest Partridge:

> *Clearly, "economic man" and "the perfect market" are severely truncated accounts of human nature and society, and thus very poor foundations for public policy-making, for practical politics, and for just provision for future generations. … And intelligent men and women will wonder how it was possible that anyone could ever have believed such nonsense.*[9]

Colin Camerer and George Loewenstein:

> *The Platonic metaphor of the mind as a charioteer driving twin horses of reason and emotion is on the right track—except that cognition is a smart pony, and emotion a big elephant.*[10]

A particularly malignant outcome of the rational patient model is the casual but all too real grouping of patients into *Good Patients* (i.e., those who follow their prescribed course of treatment ***and*** get better), *Bad Patients* (i.e., those who do not follow their prescribed course of treatment although they are capable of understanding the doctor's advice, apparently because they are spitefully oppositional), and *Pitiful Patients* (i.e., those not bright enough to understand the wisdom of the treatment plan or not functional enough to execute that plan).

This de facto classification can cause clinically and ethically flawed practices. For example, the fear that nonadherence to the anti-HIV medication cocktails causing the development of treatment-resistant HIV strains combined with the notion of bad or pitiful patients (who are noncompliant in either case) has sometimes led to recommendations that these drugs be withheld in certain cases, usually designated by the presence of race, ethnicity, socio-economic class, or history of substance abuse, factors believed – inaccurately – to be predictive of poor compliance.[11]

Replacing the idea of a patient who is perfectly rational with a more realistic hypothesis that accounts for other, non-intellectual influences is an essential step toward understanding compliance management.

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